caBIG Strategic Planning Meeting
November 8, 2004

Clinical Trials Management Systems Workspace

Joyce C. Niland, PhD
Chair, Information Sciences
City of Hope National Medical Center

Clinical Trials Management Systems (CTMS) Workspace

6 CTMS Special Interest Groups (SIGs) established:

SIG:	Led by:
Financial Data	Jill Kuennen, Univ of Iowa
Laboratory Data	John Speakman, Memorial SK
CDUS/CTMS	Rhoda Arzoomanian, Univ of Wisconsin
caBIG Compatibility	Teri Melese, UCSF
Structured Protocol	Doug Fridsma, Univ of Pittsburgh
Adverse Events	Joyce Niland, City of Hope

Financial Data SIG (from Jill Kuennen)

Purpose of the SIG:

- To develop financial/billing software modules that will meet identified needs and requirements of the Cancer Center community in a caBIG compatible way

Financial Data SIG: Accomplishments

Accomplishments to Date:

- Reviewed existing systems (City of Hope, U Pitt)
- Created list of desired functionality
- Developed use case (Univ of Iowa, Georgetown)
- Drafted high-level model of electronic financial system (U Pitt)
- Drafting description of the financial/billing project
- Recruited participation from local financial representatives

Financial Data SIG: Goals

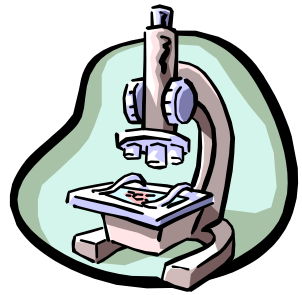
One Year Goals

- While focusing on the Trial Financial Ledger,
  - Drill down further into the **Use Cases**
  - Create **list of the data elements** flowing between study calendar
    and the financial entity at the Cancer Center
  - Create a **glossary** defining financial terms
  - Describe **interactions among components** of the model
  - Describe the **functional requirements** of each component
  - Develop functional requirement and **specification documents**
  - Develop **Statement of Work (SOW)**

Financial Data SIG: Goals

Three Year Goals

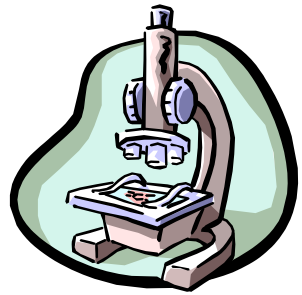
- Execute SOW:
  - Develop **risk management plans**
  - **Load CDEs** into ISO11179-compliant metadata repository
  - Create a **test approach** for ‘white box’ testing
  - **Implement** software features
  - Execute **testing** approach
  - Create **User Documentation** and installation guides
  - Create **training plan**
  - Deploy software to **adopter sites** and train sites



Laboratory Data SIG (from John Speakman)

Purpose of the SIG:

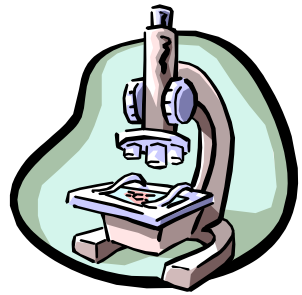
- To collaborate on the design and development of:
  1) An interface between Cancer Center clinical lab systems and caBIG-compatible clinical trials database systems to enable transfer of lab data, and
  2) A database format that facilitates sharing of de-identified laboratory data over the caBIG grid.



Laboratory Data SIG: Accomplishments

Accomplishments to Date:

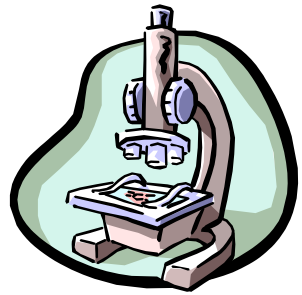
- Intensive group **discussions on data extraction** from clinical lab systems by patient, test, and date
- Formed two **subgroups** within the SIG
  - Laboratory data transfer to the clinical trials system
  - Sharing de-identified lab data across the grid
- Conducted CTMS **survey** of Center's capabilities, requirements, and preferences with respect to managing lab data
- Approached 2 clinical **lab system vendors** RE: caBIG collaboration
- Began feasibility evaluation of **adopting CDISC** model for Periodic Reporting of Clinical Trial Data
  - Has been adapted to become HL7 v3 message and ANSI standard
  - Began dialogue with CDISC on achieving harmonization in this area



Laboratory Data SIG: Goals

One Year Goals

- Identify any needed CDISC modifications, and work with CDISC to make them
- Understand from vendors what is needed to collaborate on HL7 v3 interface for transmitting CT lab messages
- Formulate plan for cooperation with Adverse Event (AE) workspace on supplying key lab data for AE reporting

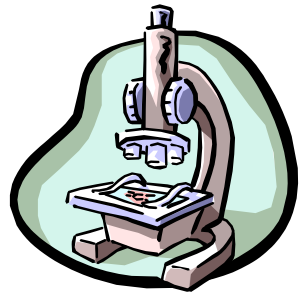


Laboratory Data SIG: Goals

Three Year Goals

- caBIG lab module should be successfully transferring lab data from at least 2 major clinical lab systems, allowing customizable filtering of data into the CTMS

- The Cancer Centers should have a means of automatic transfer of lab data into clinical trials databases without rekeying data



Laboratory Data SIG: Goals

Five Year Goals

- caBIG lab module should be supplying de-identified lab data to the grid

- A toolkit should be available to facilitate development of an interface for data transfer from any clinical laboratory system

CDUS/CTMS SIG

Purpose of the SIG:

To provide caBIG-compatible reporting of clinical trials data to the NCI-CTEP Clinical Data Update System (CDUS) and the CTEP contracted Theradex Clinical Trial Management System (CTMS)

CDUS/CTMS SIG Activities

Activities to Date:

- Determined issues and desired functionality surrounding processes of CDUS / CTMS reporting via CTMS survey (jointly with AE SIG)
- Working with CTEP to improve secure reporting channels with definitive feedback to sending institution
- Mapped proposed CTEP simplified disease classification terms to concepts in NCI thesaurus

caBIG AE and CTMS/CDUS SIGs

Adverse Event, CTMS, CDUS Reporting Systems Survey

Name of Institution: _____

Name of person completing the survey: _____

Email Address: _____

Telephone Number: _____

Date: _____

Adverse Event Reporting

Do you have any legacy Adverse Event (AE) Reporting systems/databases? ☐ Yes ☐ No

If Yes, how many? _____ (Please complete pages 3 and 4 for each legacy AE reporting system/database. Make copies as needed to complete for each legacy system.)

How do you intend to interact with the caBIG Adverse Event system:

☐ Full Implementation

☐ Interface legacy systems with the caBIG Adverse Event system

☐ Other, please describe:

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A141 =

		N	%	N	%
Total Number of Responding Institutions		**18**			
Number of Centers with Legacy System(s)		**16**	**89%**		
Total Number of Legacy Systems				**18**	
Type of AE Data Collection (Current System) (N=18)					
AE Grade				16	**89%**
AE Expectedness				10	**56%**
AE Attribution				16	**89%**
AE relatedness to the Protocol				11	**61%**
CTCAE Toxicity				11	**61%**
Protocol Status				15	**83%**
Study Phase				16	**89%**
Risk-Benefit relationship of the research				6	**33%**
Other				4	**22%**
None/No response				1	**6%**
Current System Functionality (N=18)					
Automated AE Grading				4	**22%**
AE Data Collection				9	**50%**
AE Reporting				6	**33%**
Messaging of SAEs				2	**11%**
Routing AEs				2	**11%**
Integrated AE Repository				9	**50%**
Vocabulary Management				4	**22%**
Participant Self-Reporting				2	**11%**
Public Access to AE Information				1	**6%**
Other				2	**11%**
None/No response				4	**22%**
Desired System Functionality (N=18)					
Automated AE Grading		6	**33%**		
AE Data Collection		3	**17%**		
AE Reporting		5	**28%**		

Survey Summary | Sheet 2 | Sheet 3 | Sheet4

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Mapping of the Proposed CTEP Simplified Disease Classification Terms to Concepts in NCI Thesaurus

Recently CTEP developed and circulated a new classification called the CTEP Simplified Disease Classification, to solicit comments. An evaluation of the proposed classification was conducted at COH to verify if the classification fits into an existing vocabulary/ontology resource. Since SNOMED CT is not a cancer specific vocabulary, the SNOMED searches did not yield suitable results in many cases. We also attempted to map the CTEP classification terms to the NCI Thesaurus. The NCI Thesaurus is an excellent vocabulary resource whose contents are oriented towards cancer, but also includes many other areas, e.g., anatomy, healthcare administrative areas, molecular genetics. It is a true ontology based on an expression language called Description Logic. Each concept can have relationships with other concepts. This has been exploited in the Thesaurus for creating rich sets of relationships in several cancer areas e.g., gastroenterology and breast.

The mapping exercise showed that the CTEP classification is sound and has significant correlation with the NCI thesaurus:

Total terms in CTEP classification	223
The CTEP classification terms with an **exact match** with an NCI Thesaurus concept	183 (82%)
The closest NCI Thesaurus concept **broader** than the term in CTEP classification	21 (9.4%)
The closest NCI Thesaurus concept **narrower** than the term in CTEP classification	11 (4.9%)
The closest NCI Thesaurus concept only **approximately matches** the term in CTEP classification	4 (1.8%)
There is **no appropriate** NCI Thesaurus concept that is even close to the CTEP term in CTEP classification	4 (1.8%)

inheritance hierarchy. "Broader" means that the NCI concept can subsume the CTEP term but has other concepts in its scope too. "Narrower" NCI concept means that that the concept that the CTEP term denotes can subsume the NCI thesaurus concept. Approximately matching NCI concept means that both the concepts are similar and often are children of the same broader concept and may have an overlap.

The discrepancies in the classification and the thesaurus may be resolved by making changes to the CTEP classification to conform to the NCI concepts. It may even be worthwhile to use the NCI thesaurus concept names for all the entities in the CTEP classification. If a semantic conflict is revealed in the changing of CTEP classification, recommendation may be made for changes in the NCI thesaurus. The NCI Thesaurus is administratively and technically amenable to such changes.

Conclusions:

1. The NCI thesaurus can be very for many of the purposes in caBIG. Also, there appears to be a consensus within the caBIG VCDE space about value of the NCI thesaurus.
2. The proposed CTEP classification is good and with little tweaking can become completely compliant with the NCI Thesaurus. The CTEP classification can be used for doing much of the reporting - this will require mapping of the classification to other vocabularies also, like SNOMED CT, ICD-03 and ICD9 CM. The Category and Sub-category entities of the classification should also be mapped to the NCI Thesaurus, which was not done in the present exercise. The CTEP also has mappings of the classification to MedDRA, legacy CTEP etc., which they may be willing to share.

The mappings can be seen in the accompanying spreadsheet.

07/16/04 Developed by Dr. Hemant Shah City of Hope National Medical Center

CTEP CATEGORY	CTEP SUB-CATEGORY	CTEP TERM	NCI Thesaurus Code	UMLS/NCI metathesaurus CUI	NCI Thesaurus Concept Name	NCI Thesaurus concept is:
AIDS-related Malignancy and Condition	AIDS-related Human Papillomavirus	AIDS-related anal cancer	C9278	CL051379	**AIDS-Related Malignant Anal Neoplasm**	Exact
AIDS-related Malignancy and Condition	AIDS-related Human Papillomavirus	AIDS-related cervical cancer	C7432	CL027978	**AIDS-Related Cervical Carcinoma**	Exact
AIDS-related Malignancy and Condition	AIDS-related Human Papillomavirus	AIDS-related HPV-related cancer, NOS	C4046	C0280734	**AIDS-Related Malignant Neoplasm**	Broader
AIDS-related Malignancy and Condition	AIDS-related Human Papillomavirus	AIDS-related HPV infections	C27852	CL055019	**AIDS-Related Human Papilloma Virus Infection**	Exact
AIDS-related Malignancy and Condition	AIDS-related Kaposi Sarcoma	AIDS-related Kaposi sarcoma	C3992	C0276535	**AIDS-Related Kaposi's Sarcoma**	Exact
AIDS-related Malignancy and Condition	AIDS-related Lymphoma	AIDS-related Hodgkin lymphoma	C9279	CL051382	**AIDS-Related Hodgkin's Lymphoma**	Exact
AIDS-related Malignancy and Condition	AIDS-related Lymphoma	AIDS-related Non-Hodgkin lymphoma	C5051	CL003540	**AIDS-Related Non-Hodgkin's Lymphoma**	Exact
AIDS-related Malignancy and Condition	AIDS-related Lymphoma	AIDS-related primary CNS lymphoma	C8284	CL030530	**AIDS-Related Primary Central Nervous System Lymphoma**	Exact
AIDS-related Malignancy and Condition	AIDS-related Malignancy and Condition, Miscellaneous	HIV test positive	C15175	C0019699	**HIV Positive**	Exact
AIDS-related Malignancy and Condition	AIDS-related Malignancy and Condition, Miscellaneous	AIDS-related complications	C4991	CL000317	**AIDS-Related Disorder**	Broader

Miscellaneous Neoplasm	Metastases, Distant (excluding specified site of origin)	Metastases to lung, NOS	C3577	C0153676	**Metastatic Neoplasm to the Lung**	Exact
Miscellaneous Neoplasm	Metastases, Distant (excluding specified site of origin)	Metastases to peritoneum, NOS	C4583	C0346989	**Metastatic Neoplasm to the Peritoneum**	Exact
Miscellaneous Neoplasm	Metastases, Distant (excluding specified site of origin)	Metastases to skin, NOS	C5629	C0153687	**Metastatic Neoplasm to the Skin**	Exact
Miscellaneous Neoplasm	Metastases, Distant (excluding specified site of origin)	Pleural effusion, NOS	C3331	C0032227	**Pleural Effusion**	Exact
Miscellaneous Neoplasm	Miscellaneous Neoplasm	Miscellaneous neoplasm, NOS				No Appropriate Match
Non-neoplasm	Non-neoplasm, Miscellaneous	Non-neoplastic condition, NOS				No Appropriate Match

CTEP CATEGORY	CTEP SUB-CATEGORY	CTEP TERM	NCI Thesaurus Code	UMLS/NCI metathesaurus CUI	NCI Thesaurus Concept Name	NCI Thesaurus concept is:
TOTAL CATEGORIES = 23	TOTAL SUB-CATEGORIES = 99	TOTAL TERMS = 228				

CDUS/CTMS SIG Goals (JCN)

One Year Goals

- Determine and thoroughly document CDUS/CTMS issues and needs via Use Cases
- Make incremental improvements to facilitate the reporting process with CTEP

Three Year Goals

- Create caBIG-compatible software module to encompass current CDUS/CTME reporting requirements
- Work with AE SIG and City of Hope to establish the denominator for mining for previously undetected patterns within an AE Data Warehouse nationwide

caBIG Compatibility SIG

Purpose of SIG:

To evaluate legacy, vendor-based, and emerging caBIG modules for compatibility with the caBIG guidelines for bronze, silver, and gold caBIG compatibility, and to conduct a ‘gap analysis’ to continually refine and enhance the compatibility guidelines

caBIG Compatibility SIG Activities

Activities to Date:

- Reviewed and provided input into the draft caBIG compatibility guidelines and levels

- With BAH, drafting statement of work for UCSF to evaluate Velos software, Memorial to evaluate legacy in-house software

caBIG Compatibility SIG Goals

One Year Goals

- Along with cross-cutting work spaces, deliver a refined caBIG compatibility guideline document that is proven to facilitate analysis of current and emerging software systems in this regard
- Determine methods for assessing whether suggestions for revision encompass needs and direction of the caBIG Architecture, Vocabulary and Strategic Planning groups
- Summarization of the ‘gap analysis’ for guidelines against future needs

Structured Protocol SIG

Purpose of SIG:

To develop and deploy a caBIG-compatible component that represents clinical trial protocols in a structured, computable fashion

Structured Protocol SIG: Activities

Activities to Date:

- Discussed nature of protocol representation over several teleconferences
- Gathered existing Use Cases from City of Hope and others
- Conducting survey of protocol functionality across CTMS

Survey for caBIG CTMS working group participants

Current approaches to registration and monitoring of clinical trials

This survey is intended to collect information for use by the caBIG Structured Protocol Representation (SPR) SIG. The SIG's focus is the development of a common representation of the information that is required to register, maintain, and report on clinical trials. This effort is intended to address current inefficiencies associated with tracking and reporting on clinical trials, and eventually to facilitate the sharing of research data among cancer institutes. Ultimately we expect to develop a clinical trial registry that allows research groups to enter and maintain clinical trials data in a standard format, to allow researchers and patients access to data about clinical trials at a wide range of centers, and to generate required reports electronically.

General

1. Please estimate the number of clinical trials your institution initiates annually, on average.

2. Please estimate the number of patients enrolled in clinical trials at your institution.

3. What kind of clinical trials data system does your institution currently use? (Check all that apply.)

   - ☐ We have no electronic data system (written log books only)
   - ☐ Spreadsheet or other non-relational electronic system
   - ☐ Stand alone relational database (e.g. Access, 4D, Filemaker Pro)
   - ☐ Commercial product (Name:) _____
   - ☐ Multi-tiered database server with dedicated client software
   - ☐ Multi-tiered database web server
   - ☐ Other (please specify): _____

4. What mode(s) do you currently use for entering data into your clinical trials system(s)? (Check all that apply.)

   - ☐ Manual entry of data

Structured Protocol SIG

Initial Goals (30 weeks):

- Identify appropriate level of granularity for protocol representation
- Determine functional requirements for effective protocol representation
- Document requirements for caBIG-compatible tools for effective protocol representation
- Develop a component of the specified module
- Plan and pilot deployment of the selected component
- Perform a detailed interoperability assessment of the specified module, with particular attention to the selected component

Adverse Event Reporting SIG

Purpose of SIG:

- Guide the development of an open source shareable software system to provide uniform expedited collection, processing and reporting of AEs

- **Challenges:**
  - Open source software development
  - Soliciting and considering nationwide input
  - Incorporating national/international standards
  - Interfacing with in-house and vendor-based systems
  - Including both Cancer Centers & agency perspectives

City of Hope's caBIG Roles

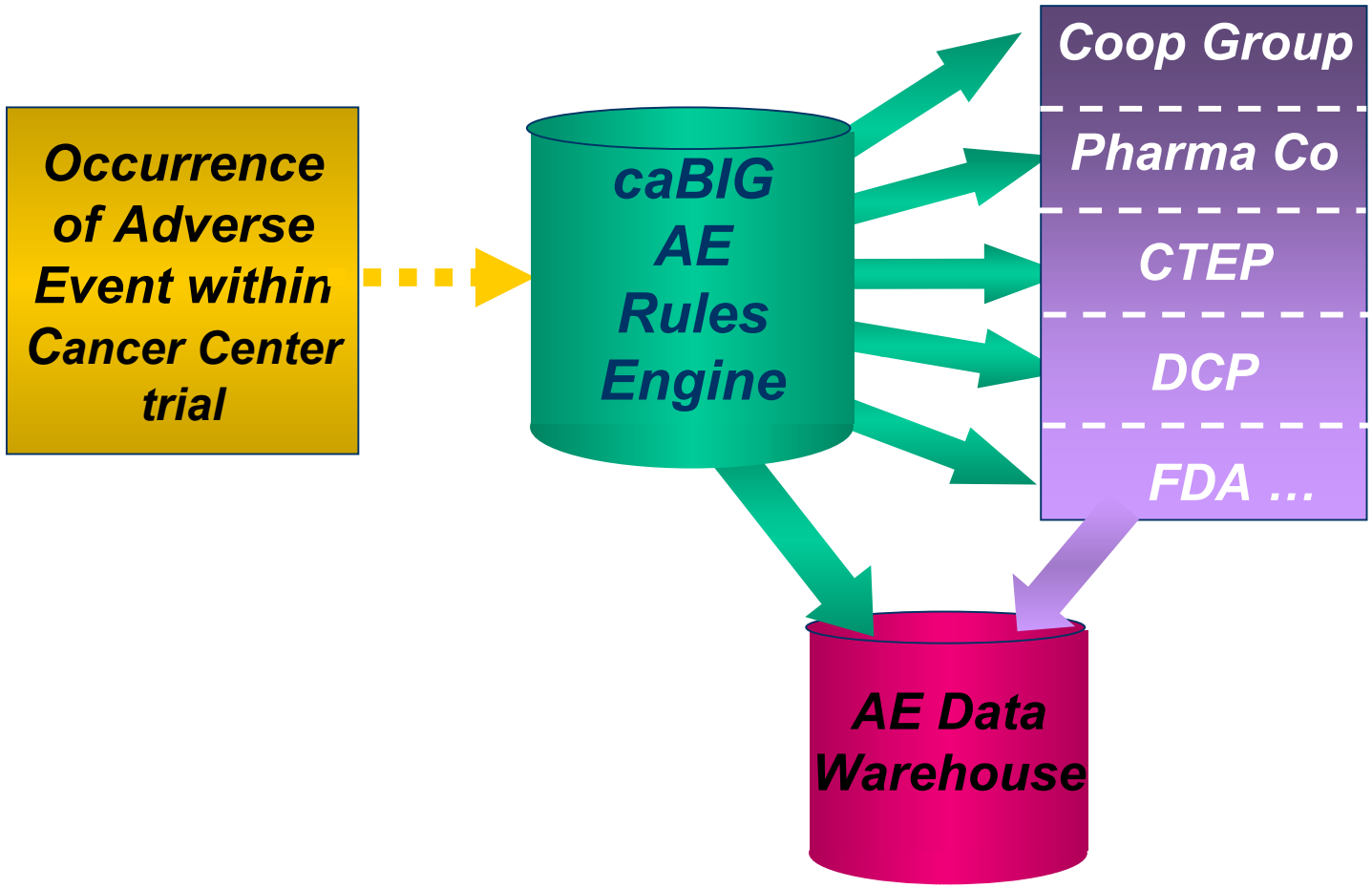
- Strategic Planning Committee Member
- Data Sharing & Intellectual Capital Committee Member
- Clinical Trials Workspace Participant
  - Leading the Adverse Event SIG
  - Volunteering in: caBIG Compatibility SIG
    Structured Protocol SIG
    CDUS/CTMS SIG
    Architecture SIG
    Vocabulary SIG
    Laboratory SIG
    Financial SIG
- Funded Developer in Clinical Trials Workspace

Adverse Event Reporting SIG

Objectives of AE Reporting Module:

- Simplify, standardize, and unify AE reporting process while making the process as efficient as possible
  - Capture and evaluate AEs
  - Route AE report internally for sign-off
  - Submit data externally for regulatory reporting
  - Provide automated decision support for AE coding
  - Allow public entry and query of AE related information
  - Provide for ‘data mining’ of AEs aggregated in a national data warehouse

caBIG AE Reporting System



Adverse Event Reporting SIG

Activities to Date:

- Assessed and contrasted functionality of existing AE software systems (ACES, AdEERS, CDUS, CSAERS, GeMCRIS, MedWatch)

Functionality of Existing Adverse Event (AE) Systems

AE System	ACES: Automated Clinical Evaluation System	AdEERS: Adverse Events Expedited Reporting System
Website	www.theradex.com/CTMS/ACES.htm	https://webapps.ctep.nci.nih.gov/openapps/plsql.gadeers_main$.startup
Developed By	Theradex	Capital Technology Information Services, Inc (CTIS)
Developed For	NCI Cancer Therapy Evaluation Program (CTEP)	NCI Cancer Therapy Evaluation Program (CTEP)
Contact Person		
Conditions Used For	Clinical Trials Monitoring Service (CTMS) Protocols but can also be used for non-CTMS protocols	Protocols using investigational agents supplied under an Investigational New Drug (IND) Application sponsored by NCI Division of Cancer Treatment and Diagnosis (DCTD).
		An event occurs on arm of a trial using both a Commercial agent and an investigational agent sponsored under an NCI IND.
		All CTEP-sponsored protocols using any type of agent (commercial, surgerical, radiation device).
		Cooperative Groups - All CTEP sponsored protocols - voluntary usage
Time Requirements for Submission	At least biweekly submissions for timely monitoring of trials in progress.	Initial online notification within 24 hours of an SAE and complete the report within 10 days for Grade 3 Unexpected Event with an Attribution of Possible, Probable, or Definite and Grades 4 and 5 Unexpected Events regardless of Attribution.
		Complete report within 10 days for Grade 2 Expected Event with an Attribution of Possible, Probable, or Definite.
Functionality	Routine AE Reporting	Expedited AE Reporting
	Captures clinical data including AE and toxicity data to submit to the CTMS - ACES is installed locally. Provides an electronic version of the NCI approved Phase I/II Case Report Form.	Collects AE data and death data unrelated to an AE via the web.
	Data are extracted and uploaded to CTMS using the distributed data transfer system - 'ACESlink'. The data may also be send to CTMS via a diskette.	Surveillance & trend analysis
	Data transfer between other ACES installations - usable for local and multi-site studies.	Generates reports
	Incorporates customized electronic Case Report Forms (CRFs).	
	Generates reports	

Adverse Event Reporting SIG

Activities to Date:

- Assessed and contrasted functionality of existing AE software systems
- Drafted data elements required to capture AE data

Fields to Capture Adverse Event Data (Draft)

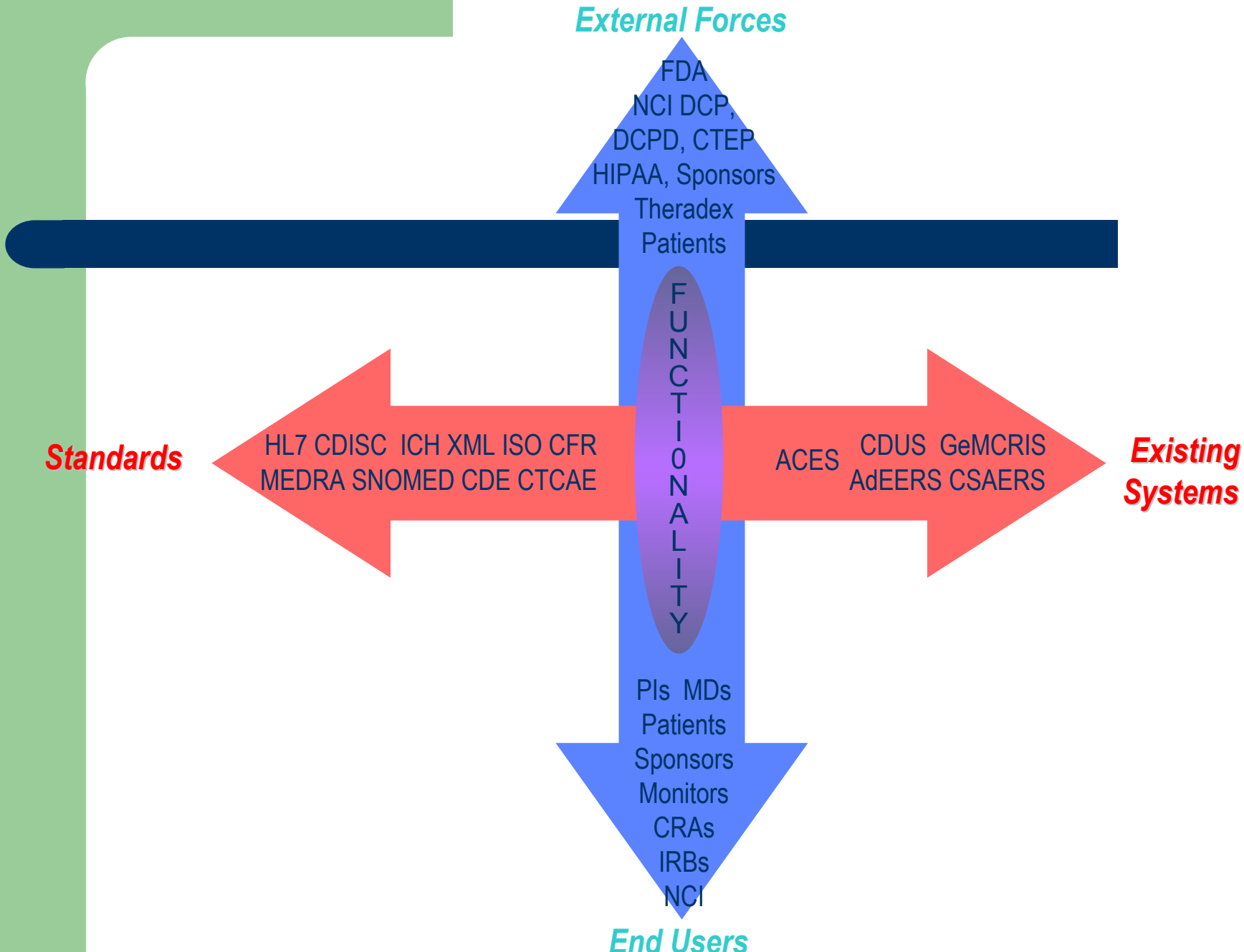
	Field	Definition
1.	Protocol ID	The unique alphanumeric identifier assigned to a protocol by the center.
2.	Participant ID	The alphanumeric identifier assigned to the participant by the center, unique within a study.
3.	Disease Code	The code to represent at a summary level the category of disease treated on a protocol (Cancer, AIDS, Benign disease), which the participant has.
4.	Subgroup Code	A code for the unique participant characteristic utilized to uniformly group patients into strata for separate analysis or treatment.
5.	Prior Chemotherapy Regiments	The previous chemotherapeutic regimens the participant has received.
6.	Treating Institution ID	The unique alphanumeric identifier for the center.
7.	Treatment On Study	The treatment as specified by the protocol.
8.	Off Treatment Reason	The reason why participant was not on the treatment specified by the protocol.
9.	Last Treatment Date	The date on which the participant last took or was administered the agent(s) of the treatment specified by the protocol.
10.	Off Study Reason	The reason why participant was removed from the study.
11.	Therapy Code	A code that specifies the type of systemic therapy the patient received.

Adverse Event Reporting SIG

Activities to Date:

- Assessed and contrasted functionality of existing AE software systems
- Drafted data elements required to capture AE data
- Identified dimensions and entities impacting caBIG AE module

Dimensions Impacting caBIG Adverse Event (AE) Module

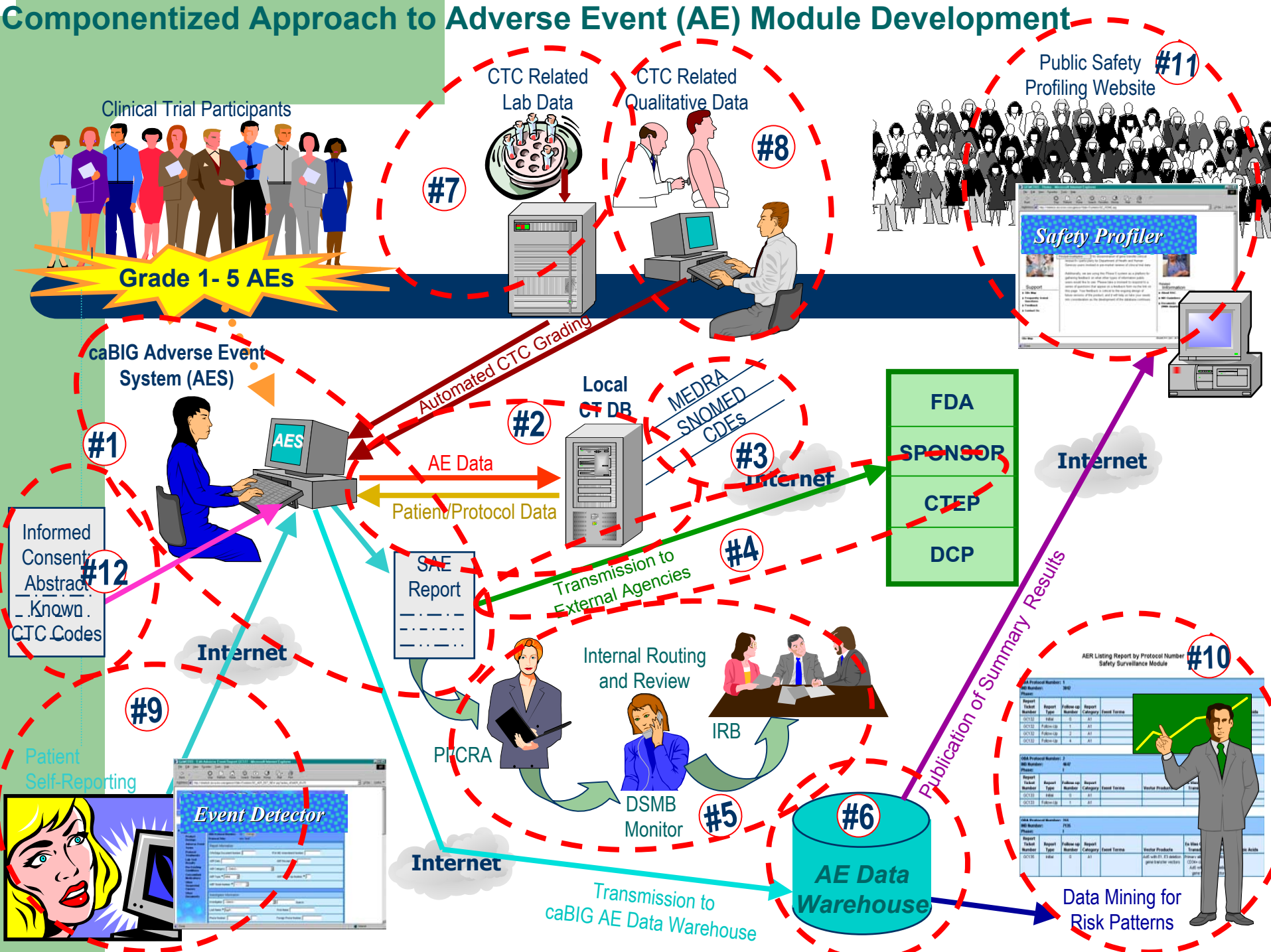


Adverse Event Reporting SIG

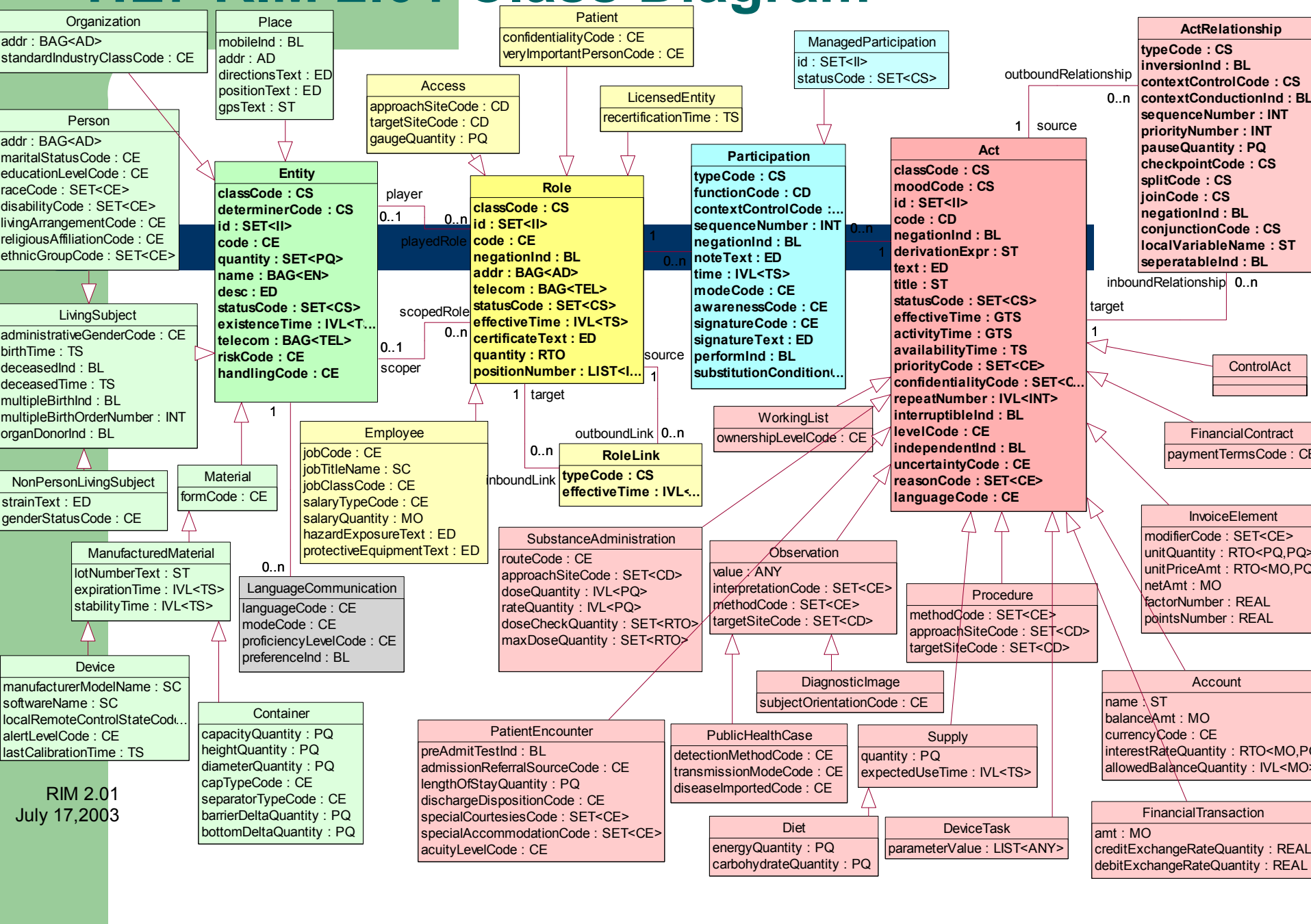
Activities to Date:

- Assessed and contrasted functionality of existing AE software systems
- Drafted data elements required to capture AE data
- Identified dimensions and entities impacting caBIG AE system
- Diagrammed and proposed staging order for modular components of AE reporting system

Componentized Approach to Adverse Event (AE) Module Development

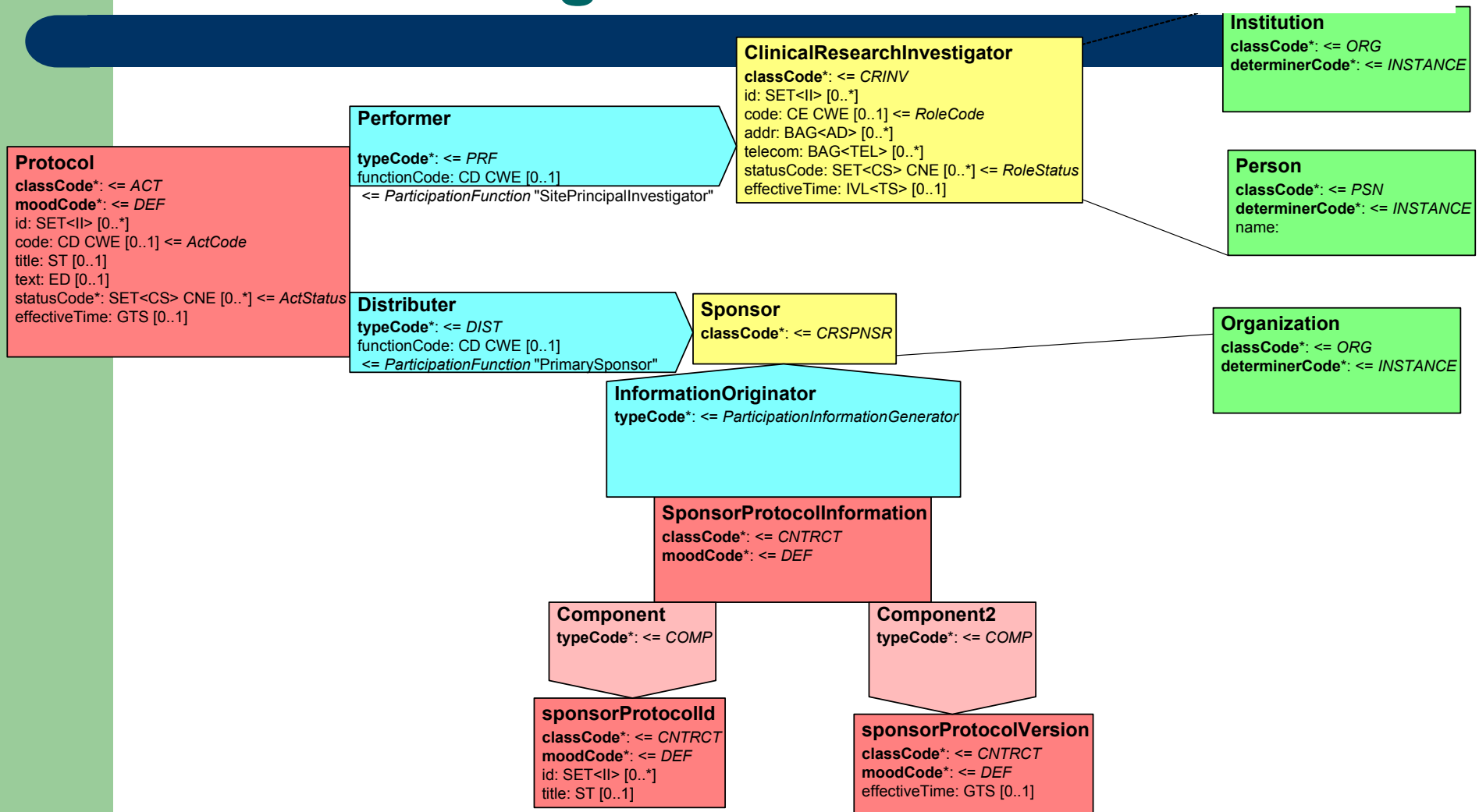


HL7 RIM 2.01 Class Diagram

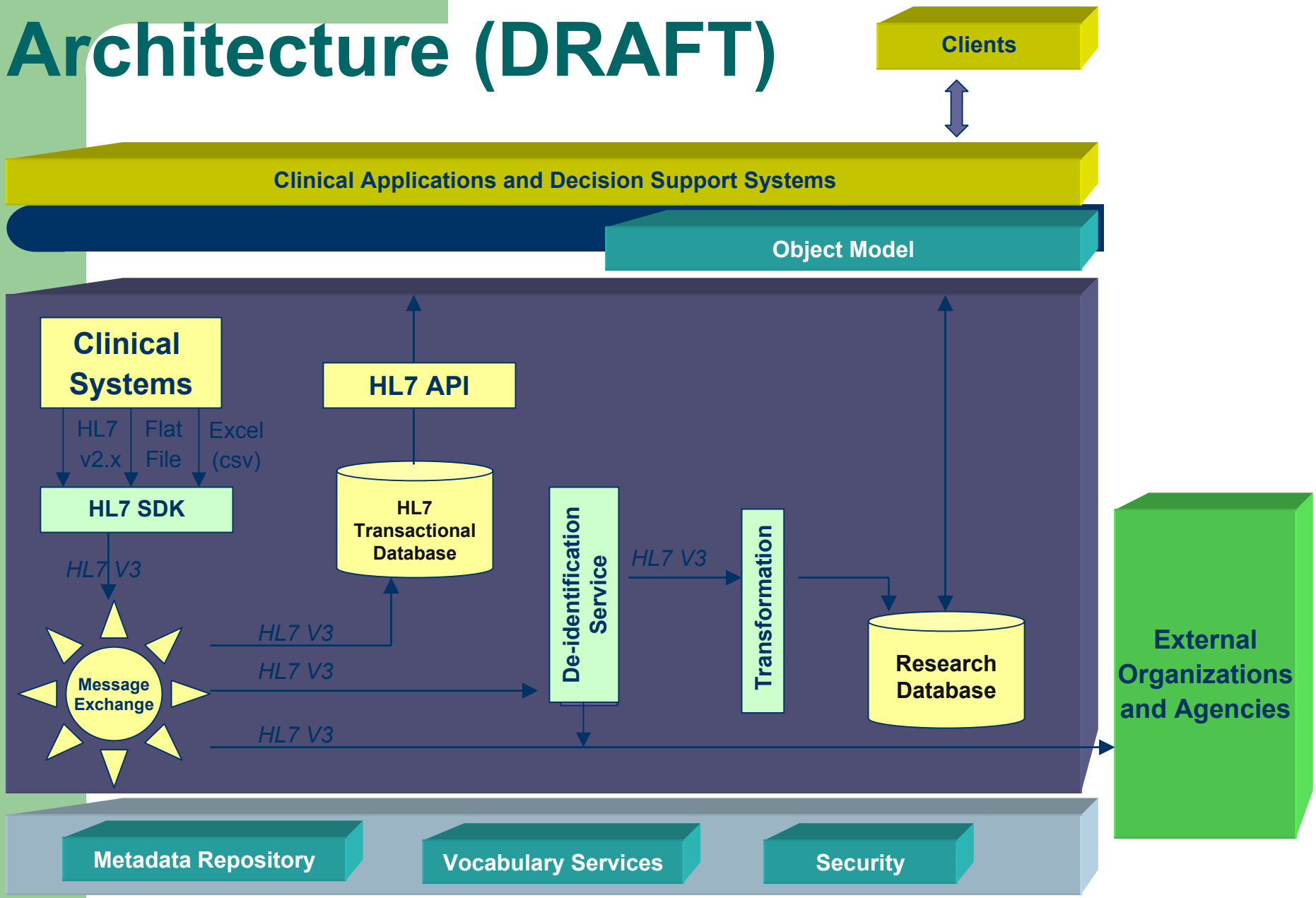


RIM 2.01
July 17,2003

FIRST Block Diagram: Protocol Registration



Clinical Trials Architecture (DRAFT)

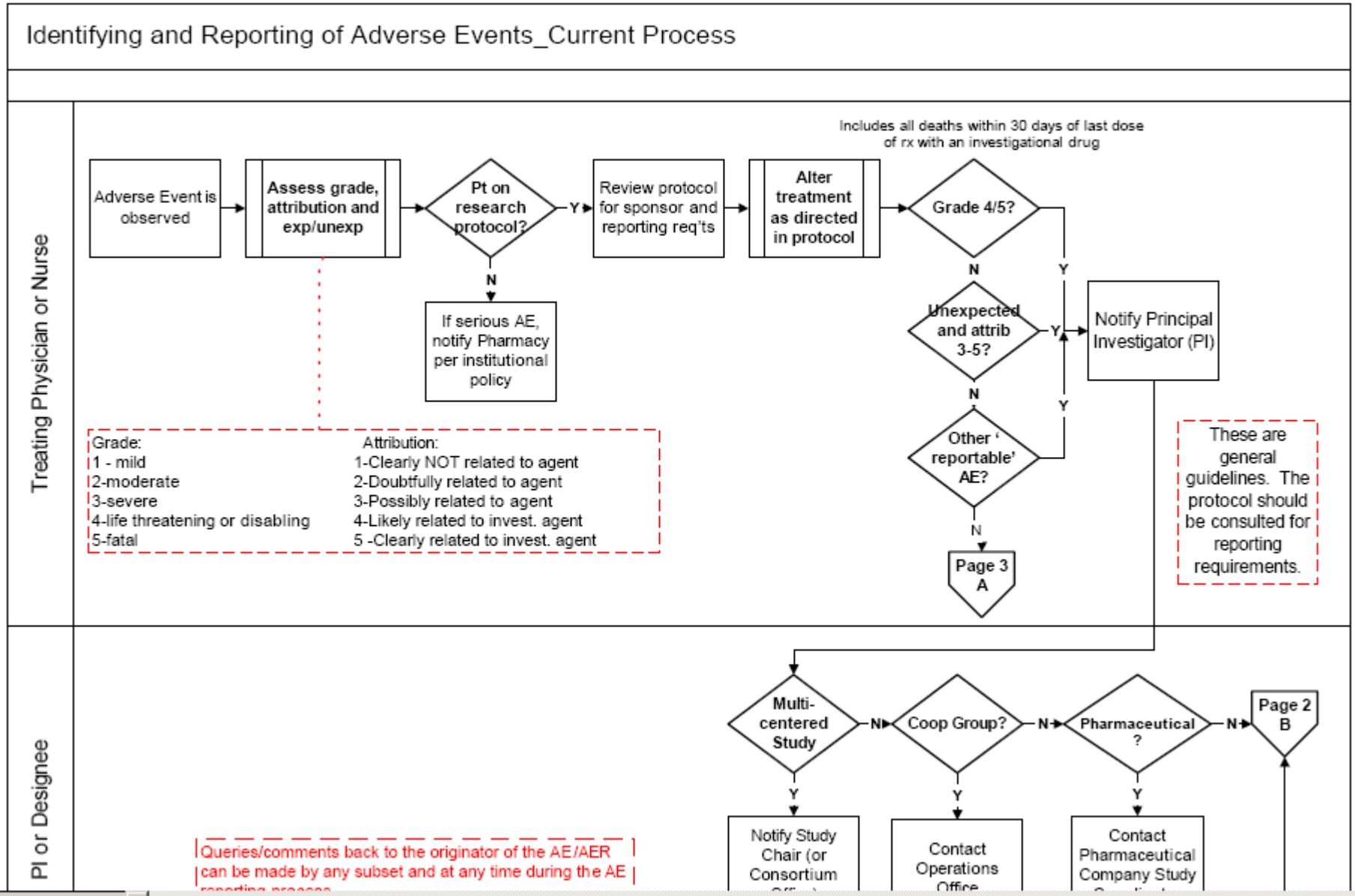


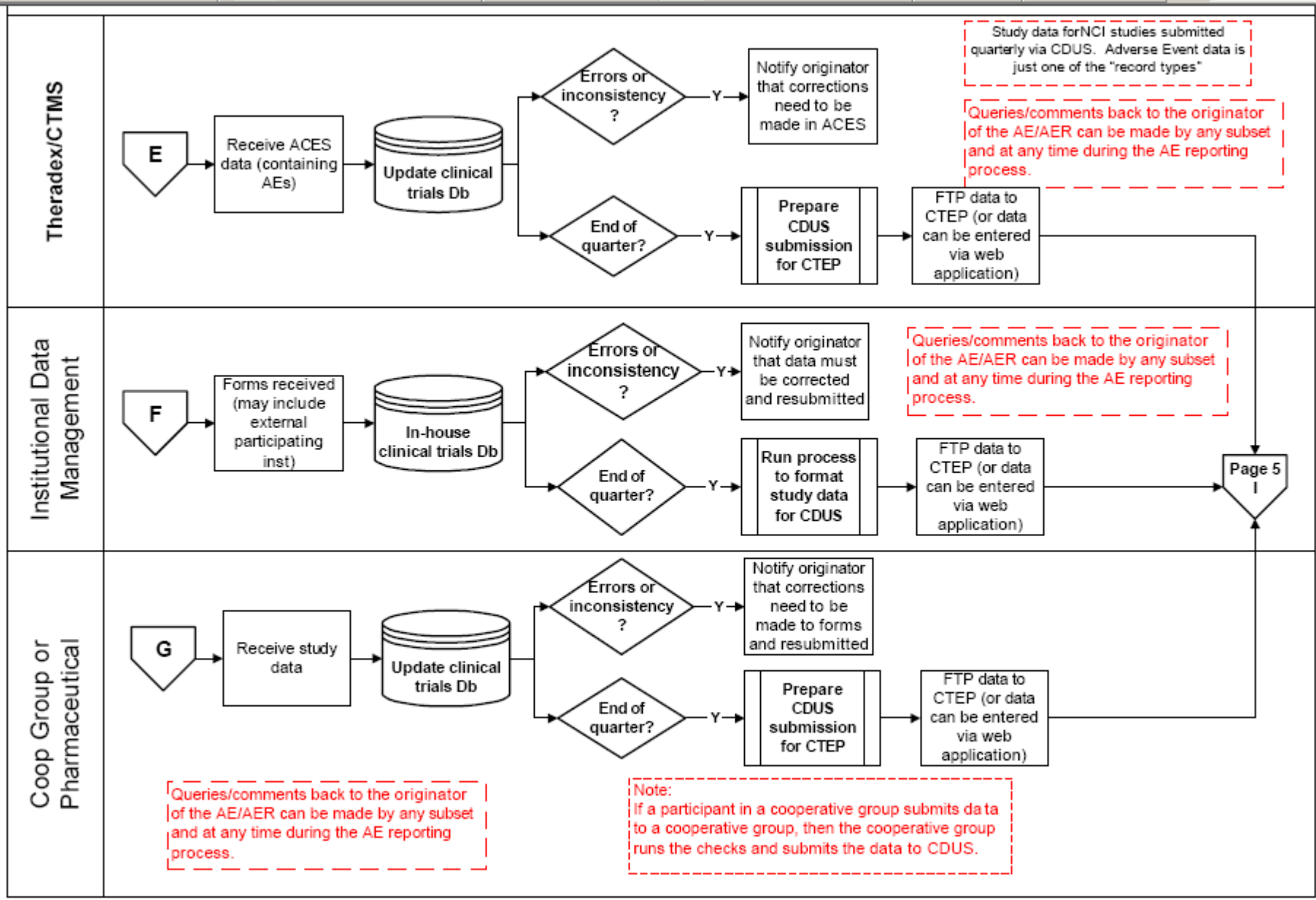
Adverse Event Reporting SIG

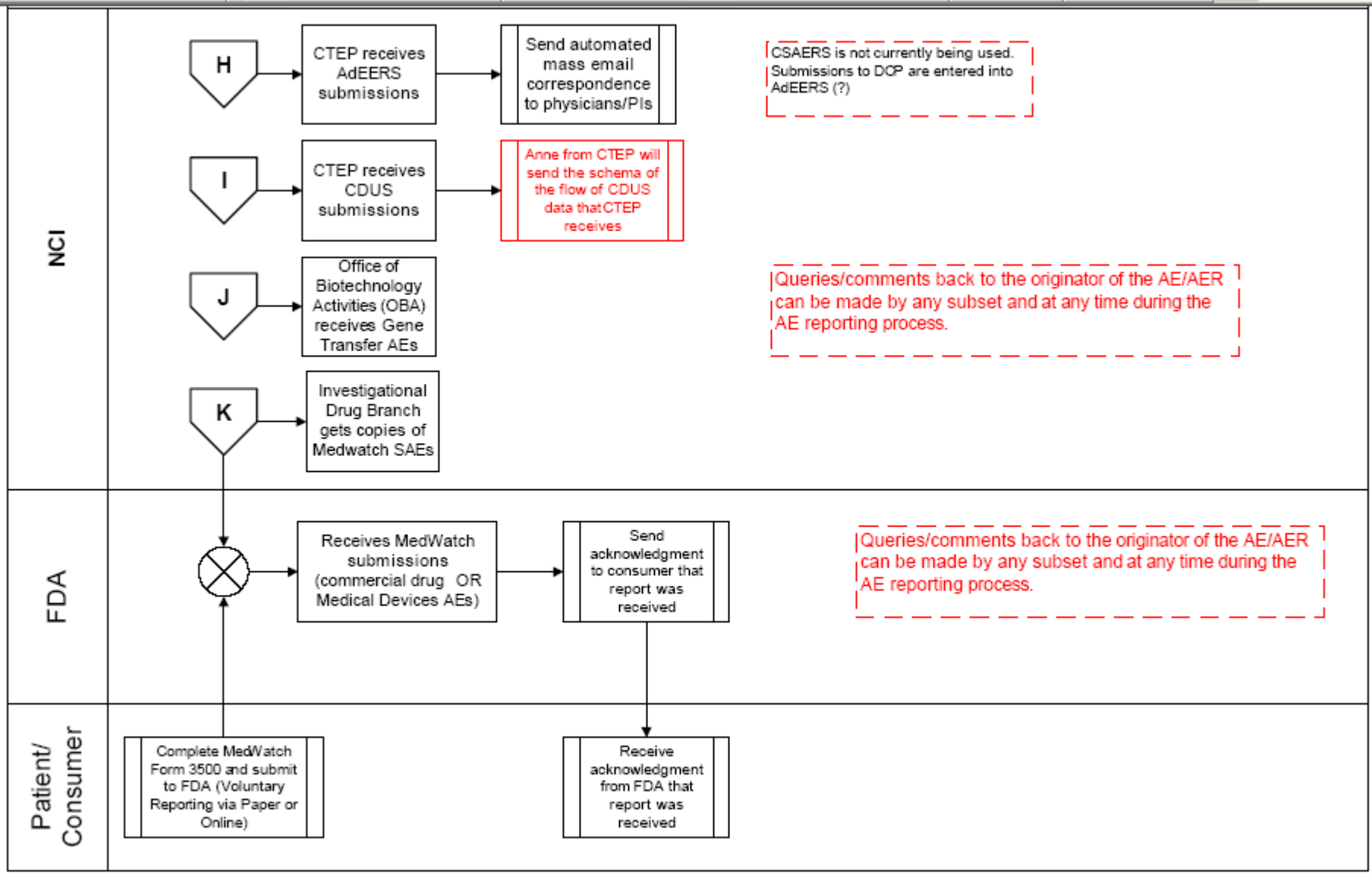
Activities to Date:

- Assessed and contrasted functionality of existing AE software systems
- Drafted data elements required to capture AE data
- Identified dimensions and entities impacting caBIG AE system
- Diagrammed and proposed staging order for modular components of AE reporting system
- Conducted high level workflow analysis of current AE reporting process from Cancer Center, Sponsor, NCI-CTEP, NCI-DCP, Theradex, and FDA perspectives

Identifying and Reporting of Adverse Events_Current Process



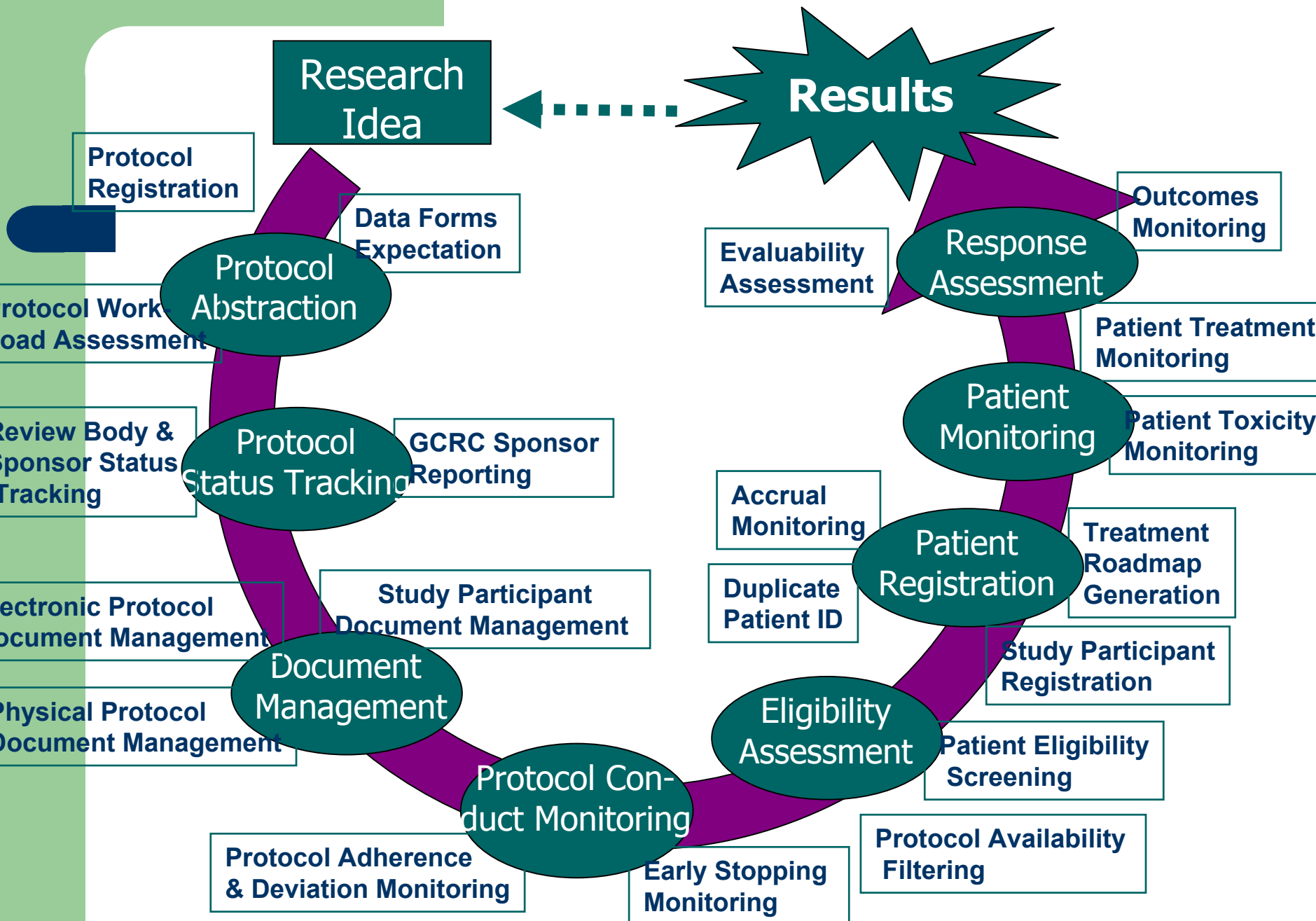




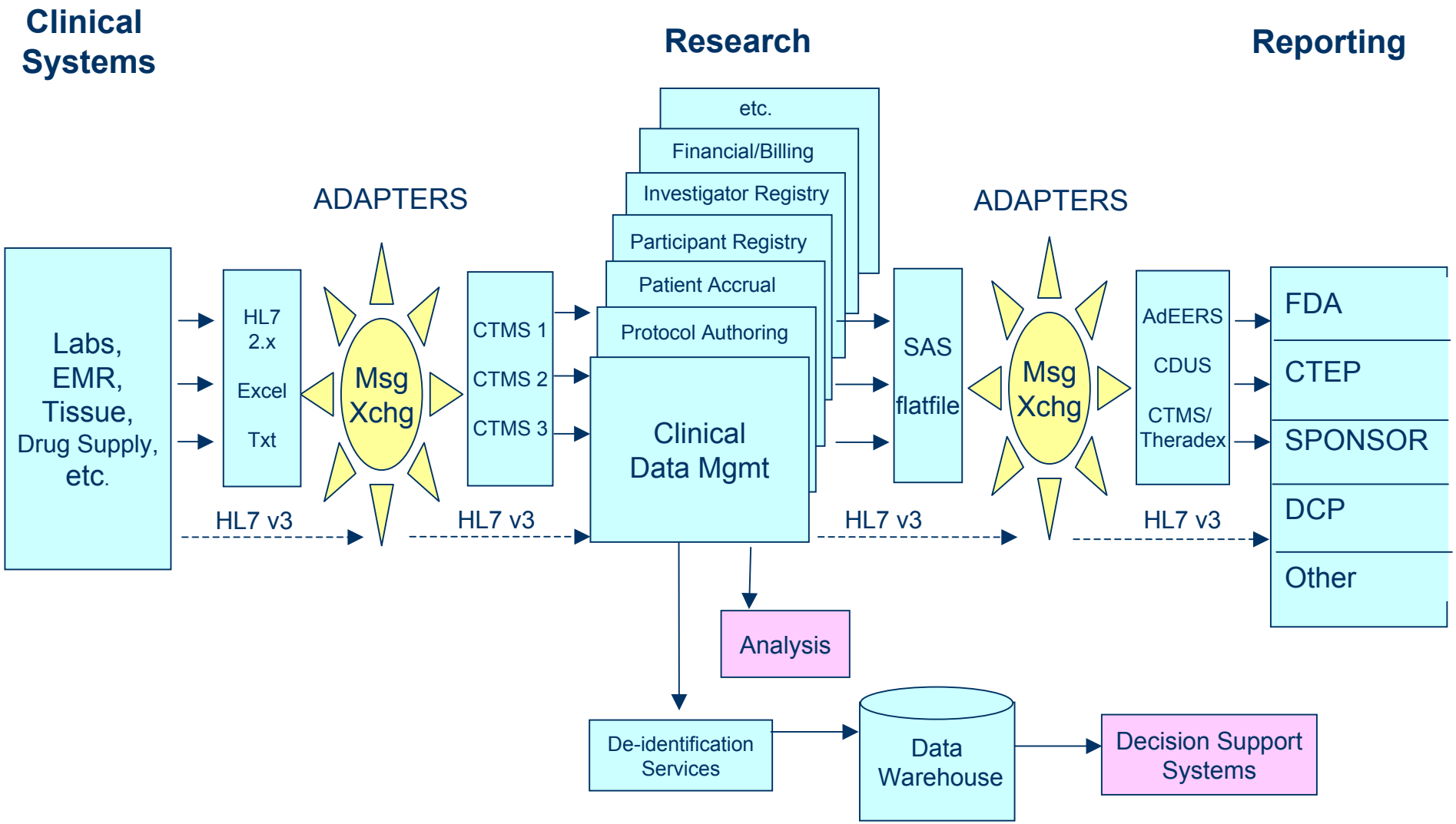
Dev by: COH National Medical Center

DRAFT - 07/15/04

Protocol Life Cycle



Roadmap (DRAFT)



Adverse Event Reporting SIG

One Year Goals

- Functional prototype for Modules 1-4 of AE Reporting system developed in caBIG compatible fashion and tested at adopter sites

Three Year Goals

- All 12 modules operational and in place at Cancer Centers, with interfaces to legacy/vendor systems, and single rules engine for electronic internal routing and external reporting to various entities

caBIG Strategic Planning

- Challenging in any setting, daunting in caBIG
- Bob Beck, September BRIITE Meeting, Seattle:
  - “Articulate a vision and drive everything to the vision” versus…
  - “Step out into the swamp and look for firm ground”

- Possible Approaches:
  - Top Down
  - Bottom Up
  - Popular Vote

Experience in caBIG to Date

Early 'Wins'

- Communication among and across stakeholders greatly increased
  - NCICB, Cancer Centers, CTEP, Theradex, DCP, FDA, etc.
- Large mobilized enthusiastic community nationwide
  - Hundreds of individuals providing input and effort
- Infusion of Cancer Center input into standard setting groups
  - CDISC, HL7 clinical research information modeling

Challenges Thus Far

- Contracting process in an academic setting
- Coordination across domain areas and "cross-cutting" workspaces (Architecture and Vocabulary)
- Involvement of entire Cancer Center community (e.g. AACI)

caBIG Strategic Planning

- Risk Matrix (Surveillance for “Gotchas”)
  - Risk, Consequence, Rank, Mitigation, Trigger, Status

caBIG Strategic Planning Working Group

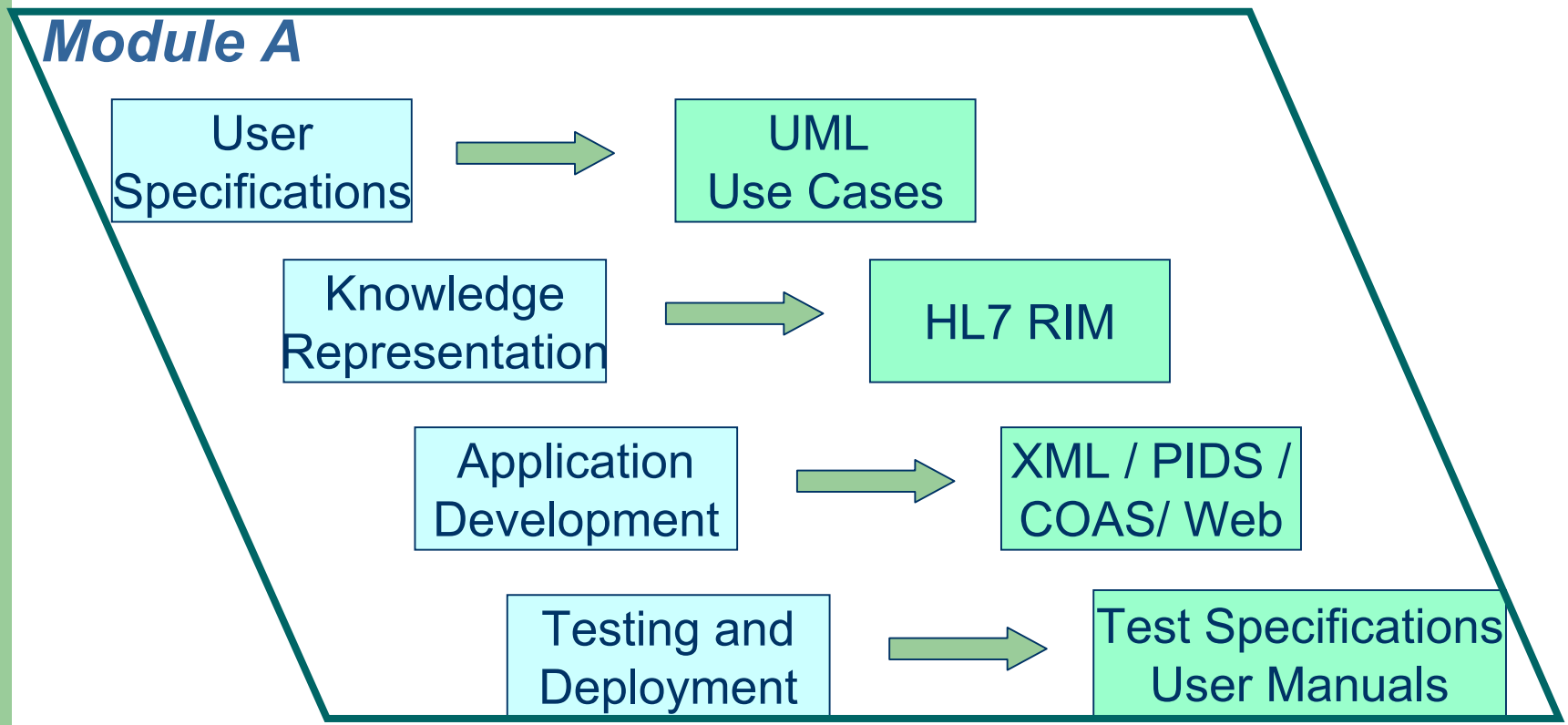
Project Risk Matrix

Risk Area	Risk	Consequence	Rank	Mitigation / Contingency	Trigger	Status
Example: *Budget Availability*	*There will be insufficient funds available to the project team to complete needed work.*	*Lack of funds will require reduction of initiative scope, or delivery of version 2 of the software within the desired timeframe may not be possible.*	*M/H*	*Project Manager will monitor budget items closely and will notify Senior Management when critical thresholds are reached.*	*>75% budget expensed in Quarters 1 or 2*	*Open*

CTMS Strategic Planning Issues

- Staging/focus of work
  - Too many simultaneous SIGs?
- Too high level definition of “caBIG”?
- How to evolve caBIG compatibility definitions?
- Role of/interactions with Oracle, other vendors
- Need for additional strategic input from CCs
- Timeliness of obtaining funding

Proposed Approach to caBIG



CTMS Strategic Planning Issues

- Communications with Cancer Center Directors
- Coordination across work spaces, SIGs
- Coordination/communication with external related groups:
  - AACI
  - CC Statisticians
  - Coop Groups
  - CTEP
  - CDISC
  - SPORES
  - Pharma
  - FDA
  - NCI CTEP, DCP, Gene Therapy, etc
  - Theradex
  - HL7 RCRIM
  - Informatics Community (eg AMIA, BRIITE)